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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/074,945	11/12/2001	Carol W. Readhead	18810-81608	8904

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EXAMINER

WOITACH, JOSEPH T

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 03/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/074,945

Applicant(s)

READHEAD ET AL.

Examiner

Joseph T. Voitach

Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on January 9, 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 135 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 135 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)             | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

This application is a divisional of application 09/191,920, filed November 13, 1998, now patent 6,316,692, which claims benefit to provisional application 60/065,825, filed November 14, 1997.

Claim 135 is pending and currently under examination.

### ***Election/Restriction***

Previously, it was indicated that this application contains claims directed to the following patentably distinct species of the claimed invention: the method is drawn to the delivery of a polynucleotide to different types of germ cells as set forth in claim 135. Applicants must elect one specific germ cell type selected from the group consisting of: (1) a spermatogonial stem cell, (2) a type B spermatogonia, (3) a primary spermatocyte, (4) a preleptotene spermatocyte, (5) leptotene spermatocyte, (6) zygotene spermatocyte, (7) pachytene spermatocyte, (8) secondary spermatocyte, (9) spermatid, and (10) spermatozoa. Each of these different cell types listed in the claim are materially different and may require different conditions for transfection and re-implantation, however each are intermediate cell types during the development of the male germ cell. Practicing the claimed method in any one of the recited cells would make obvious each of the remaining cell types. While each cell type recited technically represents a different type of cell, it would not constitute an undue burden to examine all the cell types because they represent a continuum of species of cells during the development of the male germ cell. Further, most of

the specific considerations for using any transfected cells would apply equally to all of the recited cells. For the reasons above, the restriction requirement is withdrawn.

Claim 135 is pending and currently under examination.

### ***Information Disclosure Statement***

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Specifically, there are multiple references cited in the specification, however none are provided or listed in an IDS. Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

### ***Double Patenting***

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claim 135 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 168-176 of copending Application No.

10/054,365. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instantly claimed method would necessarily result in the transgenic animal of '365. Importantly, it is noted that claim 168 requires practicing the instantly claimed method. While claim 168 does not indicate it is a method of gene therapy as set forth in the preamble of the instant claim, there is nothing in claim 135 that distinguishes it as a gene therapy method, or that distinguishes it as providing any other transgenic animal than that of claim 168 of '365.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim 135 is rejected under 35 U.S.C. 102(e) as being anticipated by Brinster (US Patent 5,858,354).

Brinster teaches a method for making a genetically altered transgenic animal wherein male germ cells are genetically altered *in vitro* and subsequently transplanted back into the seminiferous tubules. The allowed claims specifically set forth transducing spermatogonia, however also teach that spermataza can be collected and used in the claimed method. Finally,

Art Unit: 1632

Brinster teaches that the claimed method can also be used and has applications in gene therapy protocols (column 11, starting at line 42). Thus, the methods taught by Brinster anticipates the instantly claimed methods.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Brinster (US Patent 6,215,039) is related to US Patent 5,858,354 and provides the same guidance and methodology of the '354 patent used in the basis of the rejection set forth above under 35 USC 102(e).

### *Conclusion*

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (571) 272-0739.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached at (571) 272-0734.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group analyst Dianiece Jacobs whose telephone number is (571) 272-0532.

Joseph T. Woitach

*Joe Woitach*  
AV1632